

Application Serial No. 10/005,646  
Attorney Docket No. 51835AUSM1  
Response to Office Action of 15 February 2005

## REMARKS

### Claim Rejections Under USC § 112

The amendment of Claim 40 is requested herein to address the Examiner's concerns. As indicated by the Examiner, support for the amendment is found on page 5, line 11 of the specification. Thus, no new matter is added by way this claim amendment.

In view of the above amendments and remarks, Applicants respectfully request withdrawal of this rejection.

### Claim Rejections Under 35 USC § 103

Claims 36-41 and 69 stand rejected under § 103(a) as allegedly being unpatentable over Webster in view of Nakamura. The Examiner alleges that one skilled in the art would be motivated to administer FGF-9 for treatment of multiple sclerosis (MS) because Webster allegedly teaches that growth factors would be useful for MS treatment if they had the ability to increase oligodendrocyte proliferation and differentiation, upregulate myelin constituents, and promote myelin regeneration of the CNS; and Nakamura et al. allegedly teach that FGF-9 is expressed in CNS cells involved in myelination where FGF-9 receptors are present and that FGF-9 stimulates cellular processes involved in myelin formation.

Applicants respectfully traverse this rejection and assert that Webster in view of Nakamura et al. do not motivate one skilled in the art to use FGF-9 for treatment of MS. More specifically, the references of Webster nor Nakamura et al., singly or in combination, do not teach or suggest the administration of FGF-9 for the treatment of MS.

The Examiner alleges that based on the "complete disclosure of Webster" one of ordinary skill in the art would clearly conclude that growth factors, including FGF molecules, would be useful in the treatment of MS." Applicants disagree with this allegation and urge that one of ordinary skill in the art would not conclude from the teachings of Webster and/or Nakamura that any and all growth factors, including FGF molecules, and more specifically FGF9, would be useful in the treatment of MS. Such speculative statements of Webster and/or Nakamura are not enabled and supported by objective evidence in the references for any specific growth factors for the treatment of any specific disease, and more particularly, are not enabled or supported by objective evidence for the use of FGF9 for the treatment of MS. At most, the speculative statements of Webster and Nakamura et al. are an invitation to try. Growth factors, including FGF molecules, have widely varying activities and functions, and the teachings of Webster and/or Nakamura et al. do not support, in particular, the use of FGF9 in the treatment of MS.

Further, the Examiner asserts that Applicants made a "citation regarding the difference in rodent cultures versus human cultures [that] raises a second grounds of argument that Webster is teaching away from the invention because in vitro data from rodent cells is not predictive of data from human cells." Applicants hereby clarify and assert that no such statement or assertion was made by Applicants, and object to the mischaracterization of Applicants original remarks.

Applicants assert that Webster teaches "In contrast to effects seen in rodent cultures, neither FGF, IGF-I nor PDGF increased proliferation of human oligodendroglia." See

Application Serial No. 10/005,646  
Attorney Docket No. 51835AUSM1  
Response to Office Action of 15 February 2005

e.g., page 114, sentence spanning columns 1 and 2 (last sentence, second full para.). Thus, Applicants assert that Webster teaches away from the use of growth factors, including fibroblast growth factors, for treatment of MS. In view of such teachings of Webster particularly regarding rodent cultures, one of ordinary skill in the art would not have been motivated to combine the teachings of Webster with that of Nakamura et al. which relate to FGF-9 in rat, because the teachings of Webster and Nakamura et al. are conflicting and inconsistent as to the activity of FGF-9 in rodents. Consequently, Applicants urge that one skilled in the art would not have been motivated to administer FGF-9 for treatment of MS based on the teachings of Webster in view of Nakamura et al.

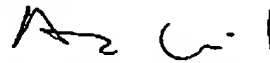
Therefore, Applicants assert that treatment of MS using FGF-9 would not have been prima facie obvious in view of the teachings of Webster in view of Nakamura et al. In view of the above remarks, Applicants respectfully request withdrawal of this rejection of Claims 36-41 and 69.

### CONCLUSION

In view of the foregoing remarks and amendments, Applicants believe that the claims are in condition for allowance and, thus, respectfully request issuance of a Notice of Allowance.

In the event that there are any questions relating to this application, the Examiner is invited to contact the undersigned patent attorney via telephone, so that prosecution of this application may be expedited.

Respectfully submitted,



Anna Gil, Reg. No. 46,726  
Attorney for Applicants

Date: 15 August 2005

**BERLEX BIOSCIENCES**  
Corporate Patents  
2600 Hilltop Drive  
P.O. Box 4099  
Richmond, CA 94804-0099

General Tel. No.: 510) 262-500  
Direct Dial Tel. No.: (510) 669-4758  
Fax. No.: (510) 262-7095